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**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

ASTRAZENECA AB, ASTRAZENECA LP,  
and POZEN INC.,

Plaintiffs,

v.

DR. REDDY'S LABORATORIES, LTD. and  
DR. REDDY'S LABORATORIES, INC.,

Defendants

Civil Action No. 3:13-cv-00091 (JAP)(TJB)

**ELECTRONICALLY FILED**

**ANSWER OF DR. REDDY'S LABORATORIES, LTD.  
AND DR. REDDY'S LABORATORIES, INC.**

Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.  
(collectively "DRL") by their attorneys, for their answer to the Complaint by AstraZeneca AB,  
AstraZeneca LP, and Pozen Inc., (collectively, "AstraZeneca" or "Plaintiffs") respond to  
allegations as follows:

**Nature of the Action**

1. DRL admits the allegations contained in paragraph 1 of the Complaint.

**The Parties**

2. DRL admits the allegations contained in paragraph 2 of the Complaint.
3. DRL admits the allegations contained in paragraph 3 of the Complaint.
4. DRL admits the allegations contained in paragraph 4 of the Complaint.
5. DRL admits the allegations contained in paragraph 5 of the Complaint.
6. DRL admits the allegations contained in paragraph 6 of the Complaint.
7. DRL admits the allegations contained in paragraph 7 of the Complaint.
8. DRL admits the allegations contained in paragraph 8 of the Complaint.

**BACKGROUND**

**The NDA**

9. DRL admits the allegations contained in paragraph 9 of the Complaint.
10. DRL admits the allegations contained in paragraph 10 of the Complaint.

**The Patent in Suit**

11. DRL denies the allegations of paragraph 11 of the Complaint, except admits that the U.S. Patent No. 6,926,907 (“the ‘907 patent”), entitled “Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs,” issued on August 9, 2005, and that the Complaint annexes a copy of the ‘907 patent as Exhibit A.

12. DRL lacks information or knowledge sufficient to admit or deny the allegations set forth in paragraph 12 of the Complaint, except that DRL admits that the ‘907 patent states on its face that the assignee of the patent is Pozen Inc.

13. DRL denies the allegations of paragraph 13 of the Complaint, except admits that the U.S. Patent No. 5,714,504 (“the ‘504 patent”), entitled “Compositions,” issued on February 3, 1998, and that the Complaint annexes a copy of the ‘504 patent as Exhibit B.

14. DRL lacks information or knowledge sufficient to admit or deny the allegations set forth in paragraph 14 of the Complaint, except that DRL admits that the ‘504 patent states on its face that the assignee of the patent is Astra Aktiebolag.

15. DRL denies the allegations of paragraph 15 of the Complaint, except admits that the U.S. Patent No. 7,745,466 (“the ‘466 patent”), entitled “Form of S-omeprazole,” issued on June 29, 2010, and that the Complaint annexes a copy of the ‘466 patent as Exhibit C.

16. DRL lacks information or knowledge sufficient to admit or deny the allegations set forth in paragraph 16 of the Complaint, except that DRL admits that the ‘466 patent states on its face that the assignee of the patent is AstraZeneca AB.

17. DRL denies the allegations of paragraph 17 of the Complaint, except admits that the U.S. Patent No. 7,411,070 (“the ‘070 patent”), entitled “Form of S-omeprazole,” issued on August 12, 2008, and that the Complaint annexes a copy of the ‘070 patent as Exhibit D.

18. DRL lacks information or knowledge sufficient to admit or deny the allegations set forth in paragraph 18 of the Complaint, except that DRL admits that the ‘070 patent states on its face that the assignee of the patent is AstraZeneca AB.

19. DRL denies the allegations of paragraph 19 of the Complaint, except admits that the U.S. Patent No. 6,369,085 (“the ‘085 patent”), entitled “Form of S-omeprazole,” issued on April 9, 2002, and that the Complaint annexes a copy of the ‘085 patent as Exhibit E.

20. DRL lacks information or knowledge sufficient to admit or deny the allegations set forth in paragraph 20 of the Complaint, except that DRL admits that the '085 patent states on its face that the assignee of the patent is AstraZeneca AB.

**The ANDA**

21. DRL denies the allegations contained in paragraph 21 of the Complaint.

22. DRL admits the allegations contained in paragraph 22 of the Complaint.

**JURISDICTION AND VENUE**

23. DRL admits the allegations contained in paragraph 23 of the Complaint.

24. DRL admits the allegations contained in paragraph 24 of the Complaint.

25. DRL admits jurisdiction and venue in this case and denies the remaining allegations in paragraph 25 of the Complaint.

26. DRL admits jurisdiction and venue in this case and denies the remaining allegations in paragraph 26 of the Complaint.

27. DRL admits jurisdiction and venue in this case and denies the remaining allegations in paragraph 27 of the Complaint.

28. DRL admits jurisdiction and venue in this case and denies the remaining allegations in paragraph 28 of the Complaint.

29. DRL admits the allegations contained in paragraph 29 of the Complaint.

30. DRL admits the allegations contained in paragraph 30 of the Complaint.

31. DRL admits the allegations contained in paragraph 31 of the Complaint.

32. DRL admits jurisdiction and venue in this case, with the balance being legal points which require no response.

33. DRL admits jurisdiction and venue in this case and denies the remaining allegations in paragraph 33 of the Complaint.

34. DRL admits the allegations in paragraph 34 of the Complaint.

35. DRL admits the allegations in paragraph 35 of the Complaint.

36. DRL admits the allegations in paragraph 36 of the Complaint.

37. DRL admits jurisdiction and venue in this case and denies the remaining allegations in paragraph 37 of the Complaint.

38. DRL admits the allegations in paragraph 38 of the Complaint.

**COUNT I**  
**(INFRINGEMENT OF THE '907 PATENT UNDER 35 U.S.C. § 271 (e)(2)(A))**

39. DRL incorporates and repeats its responses to paragraphs 1-38 above as if set forth here.

40. DRL denies the allegations of paragraph 40 of the Complaint, except admits that it sent a Notice of Paragraph IV Certification, dated November 20, 2012.

41. DRL admits that it was aware of the text of the 21 U.S.C. § 355(j)(2) and 21 C.F.R. § 314.95 (c) and denies the remaining allegations in paragraph 41 of the Complaint.

42. DRL denies the allegations contained in paragraph 42 of the Complaint.

43. DRL denies the allegations contained in paragraph 43 of the Complaint.

44. DRL denies the allegations contained in paragraph 44 of the Complaint.

45. DRL denies the allegations contained in paragraph 45 of the Complaint.

46. DRL denies the allegations contained in paragraph 46 of the Complaint.

**COUNT II**  
**(INFRINGEMENT OF THE '504 PATENT UNDER 35 U.S.C. § 271 (e)(2)(A))**

47. DRL incorporates and repeats its responses to paragraphs 1-38 above as if set forth here.

48. DRL denies the allegations of paragraph 48 of the Complaint, except admits that it sent a Notice of Paragraph IV Certification, dated November 20, 2012.

49. DRL admits that it was aware of the text of the 21 U.S.C. § 355(j)(2) and 21 C.F.R. § 314.95 (c) and denies the remaining allegations in paragraph 49 of the Complaint.

50. DRL denies the allegations contained in paragraph 50 of the Complaint, except admits that its Notice of Paragraph IV Certification, dated November 20, 2012, does not allege non-infringement of claims 1-3, 5-7, and 10 of the '504 patent, based on the information available to DRL as of the time of the service.

51. DRL denies the allegations contained in paragraph 51 of the Complaint.

52. DRL denies the allegations contained in paragraph 52 of the Complaint.

53. DRL denies the allegations contained in paragraph 53 of the Complaint.

54. DRL denies the allegations contained in paragraph 54 of the Complaint.

55. DRL denies the allegations contained in paragraph 55 of the Complaint.

**COUNT III**  
**(INFRINGEMENT OF THE '466 PATENT UNDER 35 U.S.C. § 271 (e)(2)(A))**

56. DRL incorporates and repeats its responses to paragraphs 1-38 above as if set forth here.

57. DRL denies the allegations contained in paragraph 57 of the Complaint.

58. DRL denies the allegations contained in paragraph 58 of the Complaint.

59. DRL denies the allegations contained in paragraph 59 of the Complaint.

60. DRL denies the allegations contained in paragraph 60 of the Complaint.

61. DRL denies the allegations contained in paragraph 61 of the Complaint.

**COUNT IV**  
**(INFRINGEMENT OF THE '070 PATENT UNDER 35 U.S.C. § 271 (e)(2)(A))**

62. DRL incorporates and repeats its responses to paragraphs 1-38 above as if set forth here.

63. DRL denies the allegations of paragraph 63 of the Complaint, except admits that it sent a Notice of Paragraph IV Certification, dated November 20, 2012.

64. DRL admits that it was aware of the text of the 21 U.S.C. § 355(j)(2) and 21 C.F.R. § 314.95 (c) and denies the remaining allegations in paragraph 64 of the Complaint.

65. DRL denies the allegations contained in paragraph 65 of the Complaint, except admits that its Notice of Paragraph IV Certification, dated November 20, 2012, does not allege invalidity of claims 2 and 4 of the '070 patent, based on the information available to DRL as of the time of the service.

66. DRL denies the allegations contained in paragraph 66 of the Complaint.

67. DRL denies the allegations contained in paragraph 67 of the Complaint.

68. DRL denies the allegations contained in paragraph 68 of the Complaint.

69. DRL denies the allegations contained in paragraph 69 of the Complaint.

70. DRL denies the allegations contained in paragraph 70 of the Complaint.

**COUNT V**  
**(INFRINGEMENT OF THE '085 PATENT UNDER 35 U.S.C. § 271 (e)(2)(A))**

71. DRL incorporates and repeats its responses to paragraphs 1-38 above as if set forth here.

72. DRL denies the allegations of paragraph 72 of the Complaint, except admits that it sent a Notice of Paragraph IV Certification, dated November 20, 2012.

73. DRL admits that it was aware of the text of the 21 U.S.C. § 355(j)(2) and 21 C.F.R. § 314.95 (c) and denies the remaining allegations in paragraph 73 of the Complaint.

74. DRL admits the allegations contained in paragraph 74 of the Complaint.

75. DRL denies the allegations contained in paragraph 75 of the Complaint.

76. DRL denies the allegations contained in paragraph 76 of the Complaint.

77. DRL denies the allegations contained in paragraph 77 of the Complaint.

78. DRL denies the allegations contained in paragraph 78 of the Complaint.

79. DRL denies the allegations contained in paragraph 79 of the Complaint.

80. DRL denies the allegations contained in paragraph 80 of the Complaint.

#### **PRAYER FOR RELIEF**

81. DRL denies that Plaintiffs are entitled to judgments and relief prayed for in paragraphs A through G of the Complaint.

#### **AFFIRMATIVE DEFENSES**

82. DRL alleges and asserts the following affirmative defenses in response to the allegations in AstraZeneca's Complaint:

##### **First Affirmative Defense** **(Non-infringement of Valid and Enforceable Claims)**

83. The manufacture, use, offer for sale, sale or importation of the product described in DRL's ANDA 204206 does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '907, '504, '466, '070 or '085 patents (collectively "patents-in-suit").



**Second Affirmative Defense**  
**(Invalidity)**

84. At least claims 1, 5, 9-17, 21-24, 28-29, 32-35, 37, 41-42, 45-48, and 50-55 of the ‘907 patent are invalid under Title 35 United States Code, including, *inter alia*, §§101, 102, 103, 112, and for double patenting.

85. All claims of the ‘504 patent are invalid under Title 35 United States Code, including, *inter alia*, §§101, 102, 103, 112, and for double patenting.

86. All claims of the ‘466 patent are invalid under Title 35 United States Code, including, *inter alia*, §§101, 102, 103, 112, and for double patenting.

87. All claims of the ‘070 patent are invalid under Title 35 United States Code, including, *inter alia*, §§101, 102, 103, 112, and for double patenting.

88. All claims of the ‘085 patent are invalid under Title 35 United States Code, including, *inter alia*, §§101, 102, 103, 112, and for double patenting.

**Third Affirmative Defense**  
**(Non-Infringement)**

89. The manufacture, use, sale, offer to sell in the United States or the importation into the United States of the product described in DRL’s ANDA 204206 does not and would not infringe any of the claims of the ‘907 patent.

90. The manufacture, use, sale, offer to sell in the United States or the importation into the United States of the product described in DRL’s ANDA 204206 does not and would not infringe at least claims 4, 8, and 9 of the ‘504 patent.

91. The manufacture, use, sale, offer to sell in the United States or the importation into the United States of the product described in DRL’s ANDA 204206 does not and would not infringe any claim of the ‘466 patent.

92. The manufacture, use, sale, offer to sell in the United States or the importation into the United States of the product described in DRL's ANDA 204206 does not and would not infringe any claim of the '070 patent.

93. The manufacture, use, sale, offer to sell in the United States or the importation into the United States of the product described in DRL's ANDA 204206 does not and would not infringe any claim of the '085 patent.

**Fourth Affirmative Defense**  
**(Prosecution History Estoppel)**

94. Claims of the patents in suit are so limited as not to cover the manufacture, use, offer for sale, sale or importation of the product described in DRL's ANDA 204206 due to the arguments, statements, representations and/or amendments made by Plaintiffs to the United States Patent and Trademark Office during the prosecution of the respective applications leading to issuance of each of the patents in suit.

**Fifth Affirmative Defense**

95. Each of Plaintiffs' allegations of infringement of each of the patents in suit under 271(a), (b), and/or (c) fails to state a claim upon which relief can be granted.


**PRAYER FOR RELIEF**

WHEREFORE, DRL prays for relief as follows:

- (a) That the Complaint against DRL be dismissed in its entirety and with prejudice;
- (b) That the Court permanently enjoin Plaintiffs from asserting any one or more of the '907, '504, '466, '070 and/or '085 patents against DRL or the purchasers of its Proposed Product;
- (c) That this case be deemed to be an exceptional case within the meaning of 35 U.S.C. § 285;

- (d) That DRL be awarded its attorney fees and costs and expenses of the suit, and;
- (e) That the Court award other and further relief as it deems just and proper.

Dated: January 11, 2013

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**CERTIFICATE OF SERVICE**

I hereby certify that on January 11, 2013, I caused a true and correct copy of Answer of Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.; Rule 7.1 Disclosure Statement; and Certification Pursuant to L. Civ. R. 11.2 to be served via e-mail and ECF upon:

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